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REMARKS

Claims 1-11 are presently pending in the Application and have been rejected by the Examiner under 35 U.S.C. § 112 and 35 U.S.C. § 103 over prior art cited by the Examiner.

Before discussing the various grounds for rejection, the Applicant first wishes to thank the Examiner for noting the mis-numbering of the claims and for correcting the claims by renumbering the claims appropriately.

Considering the various grounds for rejecting the claims, the Examiner has rejected claim 6 under 35 U.S.C. § 112 for lack of antecedent basis for the terms "the analysis mechanism" and "aspiration tube". In response, the Applicant has amended claim 6 herein above to correct any lack of antecedent basis for the recitations of the claim. The Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claim 6 under 35 U.S.C. § 112.

Next considering the rejections of the claims under 35 U.S.C. § 103, the Examiner has rejected claims 1, 11, 2, 7-9, 3 and 10 over Marsoner et al. '157 in view of the Applicant's statement and further in view of Ito '028, and has rejected claims 1 and 3-5 under 35 U.S.C. § 103 over Marsoner et al. '157 in view of either Berger et al. '314 and Marcote et al. '450 and in further view of Applicant's statement and in further view of Ito '028.

In response, it will be seen from the above amended claims and from the following discussions that the Applicant has amended the claims to more explicitly define the invention as recited in the claims over the cited prior art under both 35 U.S.C. § 102 and 35 U.S.C. § 103. It will be noted that these amendments do not add any new matter to the specification or claims and do not change, modify or extend the actual subject matter of the claims in any way, and do not in any way alter the direction of the claims.

First considering the present invention as recited in claims 1-11 and as described in the specification, as recited in claims 1 and 2 the present invention is directed to a modular automated diagnostic analyzer having a modular sensor chamber and a fluid passage for conducting fluids to the sensor chamber wherein the sensor chamber includes one or more

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removable sensor modules for performing analysis tests on the samples. According to the present invention, each sensor module includes one or more multiple use thick film sensors, a record memory for storing information pertinent to the sensor module, and a processing unit, which may be associated with the sensor module, with the analyzer as a unit, or with the record memory, for reading and writing information pertaining to the sensor module from and to the record memory.

Other aspects of the present invention, for example as recited in claims 3 and 4, are that each sensor module includes a fluid passage through a sensor module chamber containing film sensor elements on a substrate, and that each sensor module is provided with a fluid tight seal at least one end of the fluid passage to form a fluid tight seal with the fluid passage of another sensor module or with the fluid passage of the analysis mechanism chassis.

Still further aspects of the present in, as recited for example in claims 6, 7 and 8, pertain to the information stored in the record memories and how the information is stored in the record memories. For example, and as recited in the claims, may include information pertaining to the primary functions of the sensor, such as use life information, including a maximum number of test uses of the sensor module, a maximum test use life of the sensor module, a current accumulated number of test uses of the sensor module, and a current accumulated test use period of the sensor module. Yet other information that may be stored in the record memories may include, for example, information identifying the sensor, the type of sensor and sensor calibration information.

The present invention also encompasses how information is stored in the record memories to best meet the information storage requirements of a sensor module. For example, and as recited in the claims, initial information pertaining to the sensor module is stored in the record memory before use of the sensor module, and sensor use information is subsequently also stored in the record memory during use of the sensor module.

Other aspects of the pr s nt invention are directed to the construction of a sensor module and an analyzer using removable and replaceable modular sensors.

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For example, and as recited in claim 5, the sensor chamber of the analyzer includes an engagement element for selectively exerting pressure along one or more sensor modules in the sensor chamber to force the fluid seals of the one or more sensor modules into contact and into contact with the fluid passage of the analysis mechanism chassis so that the fluid passages of the one or more sensor modules form a single gas and liquid tight passage through the sensor chamber.

Other aspects of the present invention are directed to further details of an analyzer using removable and replaceable modular sensors. For example, it is described in the specification and recited in the claims that the analyzer includes a fluid entry module rotatably mounted to the analysis mechanism and enclosing the fluid passage, which conducts fluids to be analyzed to the sensor chamber. The fluid entry module further includes an entry port for the entry of fluids to the sensor chamber through the fluid passage and a wiping seal mounted in the fluid entry module and slidably enclosing the aspiration tube in a region extending from the fluid entry port. As described and as recited in the claims, the fluid entry module is rotatably and slidably engaged with an analysis mechanism chassis so as to be rotatable to a plurality of fluid entry positions. The rotation of the fluid entry module results in a sliding motion of the above discussed wiping seal with respect to the entry port, due to rotation of the fluid entry module between fluid entry positions, so that the wiping seal operates to remove any residue of aspirated fluids from exterior surfaces of the entry port.

In still further aspects of the present invention, a given sensor module may include one or more multiple use thick film sensors operating as a reference, or may include one or more multiple use thin film sensors instead of, or in addition to, the thick film sensors.

Now considering the prior art cited by the Examiner in the rejection of claims 1, 11, 2, 7-9, 3 and 10 over Marsoner et al. '157 in view of the Applicant's statement and further in view of Ito '028, the Applicant first wishes to clarify the intent and meaning of the Applicant's statement with regard to the present Invention. As described herein above, the Applicant does not claim thick or thin film sensors or record memories with associated processors per se.

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The present invention is instead directed to the combination of a modular sensor with film sensors and record memories incorporated into each modular sensor, and to the combination of such modular sensors with a modular analysis apparatus of the type described and claimed in the application. As such, it will be seen that the intent and purpose of the Applicant's statement is to provide necessary information about the design, construction and use of known elements, that is, the film sensors and record memories, that are used in combination with other elements to create the present Invention as described and claimed in the present application. The Applicant is not claiming thick or thin film sensors or record memories in themselves, but is instead claiming the combination and use of such elements with other elements to create a new invention.

Next considering the teachings of Marsoner et al. '157, the analyzing apparatus taught by Marsoner et al. '157 includes a measuring unit (1) containing several measuring cells (5, 5') which are linked by a channel (6) wherein measuring probes of various types are mounted in the measuring cells and connected to external circuitry and wherein the ends of the measuring unit are provided with seals 15 to enable the measuring unit to be coupled to other units or to electrode units. In essence, therefore, the measuring unit of Marsoner et al. '157 comprises a sensor chamber in itself, including, within a single structure, the external framework structure of a sensing chamber, a continuous passage for fluid samples, and a plurality of sensors with electrical connections located within cells in the continuous fluid passage and wherein Marsoner et al. '157's sensor chamber, or measuring unit, may be mated with an analysis apparatus or other elements, such as other measuring units or electrode units. Expressed another way, it is clear that Marsoner et al. '157's measuring unit does not correspond in structure or function to the modular sensor modules of the present invention, wherein each sensing element contain one or more film sensor elements and a record memory and wherein the sensor modules are separate and independent unit that may be individually and separately installed in or removed from the sensor chamber, such as to select the functions performed by the apparatus.

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Instead, and in fundamental contrast from the present invention as recited in claims 16-22, the structure taught by Marsoner et al. '157 is one that would result if a plurality of the modular sensor modules of the present invention were constructed as a single, unitary, monolithic structure having a fixed number and configuration probes and wherein the probes could be changed only by effectively rebuilding or replacing the entire measuring unit.

In this regard, it must be noted that Marsoner et al. '157 neither shows nor mentions any form of measuring unit constructed as an independent modular unit having a single sensing cell and one or more sensors, but describes only unitary, monolithic measuring units constructed as a single unit and containing multiple sensing cells and multiple probes. The multiple cell structure is, in fact, fundamental to the teachings of Marsoner et al. '157 as being the only implementation taught or shown by Marsoner et al. '157 and because of the design constraints and considerations discussed at length by Marsoner et al. '157, for example, at column 3, line 49 through column 4, line 61, wherein Marsoner et al. '157 discusses the problems of sealing the unit against air bubbles and providing electrical isolation of the probes.

In fact, it is an obvious conclusion that while Marsoner et al. '157 recognized the need for joints for connections between measuring units and other components of the apparatus, Marsoner et al. '157 concluded that the number of such joints should be minimized while allowing some modularity of assembly. As such, it is a further obvious conclusion that Marsoner et al. '157 did not realize, in contrast from the present invention, that an adequately sealed assembly of modular sensor modules could be constructed using modular sensor modules wherein each module contains a single sensor element and, in this respect, effectively teaches away from the present invention.

It is the belief and position of the Applicant that the present invention as recited in claims 1-11 as amended herein is fundamentally and patentably distinguished over the teachings of Marsoner et al. '157 under the requirements of 35 U.S.C. § 103.

Next considering Ito '028, Ito '028 describes a film biosensor with a record memory for storing data pertaining to the film biosensor. Again, however, and as discussed above with

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regard to the Applicant's statement, the claims of the present application are not directed to film sensors per se, or even to film sensors with record memories, but are instead directed to the combination of sensor modules containing film sensors and record memories with an analyzer constructed to use such sensor modules. More specifically, the film sensors and record memories are claimed only in combination with a sensor module having the characteristics described in the specification and recited in the claims, and further in combination with an analysis apparatus as described in the specification and as also recited in the claims.

It is the belief and position of the Applicant that the teachings of Ito '028, like the Applicant's statement, are not relevant to the present invention as claimed but represent only specific implementations of certain of the devices employed as one of the elements of the present invention.

It is further the belief and position of the Applicant that the Applicant's statement and the teachings of Ito '028 do not teach or suggest the present invention as claimed and that the teachings of Marsoner et al. '157, as discussed above, do not teach or even suggest the present invention to those of ordinary skill in the art under 35 U.S.C. § 103, and in fact teach directly away from the present invention in many respects. It is the belief and position of the Applicant that the combination of Marsoner et al. '157 with the Applicant's statement in further view of Ito '028, can not and do not teach or suggest the present invention to one of ordinary skill in the art under the requirements and provisions of 35 U.S.C. § 103. The Applicant respectfully requests that the Examiner reconsider and withdraw all rejections of the claims as amended herein above, under 35 U.S.C. § 103, and the allowance of the claims as amended herein.

Next considering the Examiner's rejection of claims 1 and 3-5 under 35 U.S.C. § 103 over Marsoner et al. '157 in view of either Berger et al. '314 and Marcote et al. '450 and in further view of Applicant's Statement and in further view of Ito '028, Marsoner et al. '157, the Applicant's statement and Ito '028 and the combination thereof have been discussed herein

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above and will not be discussed in detail in the following to avoid repetition. Instead, the discussions of Marsoner et al. '157, the Applicant's statement and Ito '028 herein above should be regarded as incorporated into the following discussions.

Considering the teachings of Berger et al. '314 and Marcote et al. '450, therefore, the Examiner cites both Berger et al. '314 and Marsoner et al. '157 a teaching chambers and ovens for the heating of sensor modules or sensor and as providing a passage for conducting fluids, further stating that it would then be obvious to add thin or thick film sensors. It is noted, although not remarked by the Examiner, that the Berger et al. '314 apparatus also includes a cooling apparatus.

First, the Applicant is confused by the citing of Berger et al. '314 and Marcote et al. '450 as teaching heated ovens or chambers for thermal control of sensor modules.

The present invention as described in the specification and as recited in the claims is not directed to, does not include and does not even mention any form of temperature control of the modular sensors. In this regard, it must be noted that the heating and cooling of film sensors of any form is very likely to prove detrimental to the sensors, and that both Berger et al. '314 and Marcote et al. '450 were conceived and published before the common advent of either thick or thin form sensors and thus it is most probable that neither of Berger et al. '314 and Marcote et al. '450 even considered such sensors.

It must also be noted that the present invention as described and claimed is directed to entirely different purposes and functions than are Berger et al. '314 and Marcote et al. '450. In this regard, it must be noted that Marcote et al. '450, at least, and possibly Berger et al. '314, is directed to the analysis of pollutants and contaminants, such as those found, for example, in a factory or power plant exhaust stack. Such pollutants and contaminants, and the conditions such as temperature at which they are gathered and analyzed would most probably be very hostile to any form of film sensor and would most probably destroy such sensors in a relatively short time.

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As far as the teachings of Berger et al. '314 and Marcote et al. '450 regarding fluid passages is concerned, Berger et al. '314 and Marcote et al. '450 are again irrelevant to the present invention and are merely cumulative over Marsoner et al. '157, which includes a form of passage for fluids or gases to be introduced to and to pass by the sensors.

Further in this regard, it must be noted that Marsoner et al. '157, Berger et al. '314 and Marcote et al. '450 are not pertinent to the present invention for the basic reason that the present invention is not directed to a fluid passage, which is only a part of the analysis apparatus that is peripheral to and that is not required by the present invention. For example, samples to be analyzed may be introduced directly to the modular sensor chamber rather than through the more complex fluid entry module and fluid passage. The recitations concerning a fluid passage, while not necessary to the present invention, directs the claims to a presently preferred embodiment of the invention.

In summary, therefore, the teachings of Berger et al. '314 and Marcote et al. '450, taken either individually or in any combination, is irrelevant to the present invention and does not pertain to the present invention in any way.

It is the belief and position of the Applicant that the teachings of Marsoner et al. '157, Berger et al. '314, Marcote et al. '450, the Applicant's statement and Ito '028 do not teach or suggest the present invention as claimed, and in fact teach directly away from the present invention in many respects. It is therefore the belief and position of the Applicant that the combination of Marsoner et al. '157 in view of either Berger et al. '314 and Marcote et al. '450 and in further view of Applicant's statement and in further view of Ito '028, can not and do not teach or suggest the present invention to one of ordinary skill in the art under the requirements and provisions of 35 U.S.C. § 103. The Applicant therefore respectfully requests that the Examiner reconsider and withdraw all rejections of the claims as amended herein above, under 35 U.S.C. § 103, and the allowance of the claims as amended herein.

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If any further amendment to this application is believed necessary to advance prosecution and place this case in allowable form, the Examiner is courteously solicited to contact the undersigned representative of the Applicant to discuss the same.

In view of the above amendments and remarks, it is respectfully submitted that all of the raised rejection(s) should be withdrawn at this time. If the Examiner disagrees with the Applicant's view concerning the withdrawal of the outstanding rejection(s) or applicability of the Marcote et al. '450, Berger et al. 1314, Marsoner et al. '157 and Ito '028 references, the Applicant respectfully requests the Examiner to indicate the specific passage or passages, or the drawing or drawings, which contain the necessary teaching, suggestion and/or disclosure required by case law. As such teaching, suggestion and/or disclosure is not present in the applied references, the raised rejection should be withdrawn at this time. Alternatively, if the Examiner is relying on his/her expertise in this field, the Applicant respectfully requests the Examiner to enter an affidavit substantiating the Examiner's position so that suitable contradictory evidence can be entered in this case by the Applicant.

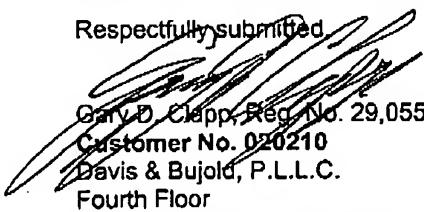
In view of the foregoing, it is respectfully submitted that the raised rejection(s) should be withdrawn and this application is now placed in a condition for allowance. Action to that end, in the form of an early Notice of Allowance, is courteously solicited by the Applicant at this time.

The Applicant respectfully requests that any outstanding objection(s) or requirement(s), as to the form of this application, be held in abeyance until allowable subject matter is indicated for this case.

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Respectfully submitted,


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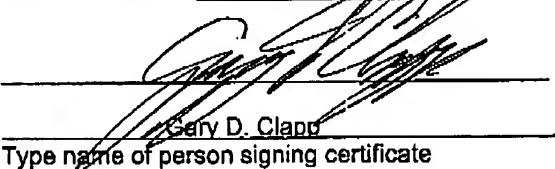
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